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Objectives: Many patients want help in considering medical information relevant to treatment decisions they have to make or agree to. The present research investigated whether focussing on particular issues relevant to a medical treatment decision (using an apparently non-directive procedure) could systematically bias a treatment decision.

Design and methods: In a randomised design, participants (community volunteers, n=146) were given standard information about treatment of cardiac risk factors by medication (statins). There were four experimental interventions in which the participants focussed on the likely personal relevance of subsets of the information previously given (positive, negative or mixed aspects) or on irrelevant information. Participants were asked to rate their anticipated likelihood of accepting treatment before and after the experimental intervention.

Results: The rating of acceptance of treatment was significantly increased by positive focussing; negative focussing did not significantly alter the decision rating.

Conclusions: The results partially replicate similar studies in health screening decisions. Reasons for the differences in results from those obtained in screening studies are considered. It is suggested that negative focussing may have less effect in decisions in which there are few risks.

Interest in shared decision making in medical treatment has stimulated research into patient preferences regarding medical consultation style. Shared decision making consists of 2 main parts: firstly the provision of information; and secondly *the process of using that information* to make the decision. Regarding this first point, results of studies considering a wide range of diseases consistently indicate that patients desire high levels of information about the treatment options available. For example, this has been shown when considering hormone replacement therapy (HRT) and pain (Wroe, Salkovskis, Rees & Jack, 2013), in rehabilitation medicine patients (Beisecker & Beisecker 1990) and cancer patients (Beaver, Campbell, Craven, Jone, Luker & Susnerwala, 2009). Furthermore, research has shown the long term benefits of involvement in the decision process regarding satisfaction (Wroe et al, 2013). Particularly the extent to which patients perceived themselves as having been prepared for the side effects of the medication has been shown, in a range of conditions including the use of HRT, and treatments for pain, HIV and asthma, to be related to long term effects, including adherence, anxiety and satisfaction (e.g. Wroe, 2002; Wroe et al, 2013; and Wroe & Thomas, 2003). In order to ensure that patients are given the opportunity to make informed and unbiased decisions, it is crucial that we understand the ways in which patients can be involved in the decision process, in a way that is not biased by the health professional involved. This study focuses on the second phase of shared decision making; that is, the way in which people use the information to make a medical decision. The research aims to improve our understanding of the ways in which “biases” might operate in the second phase of decision making, using the theoretical framework of the modified Subjective Expected Utility Theory (Wroe, Salkovskis & Rimes, 1998).

The modified subjective expected utility model (Wroe, Salkovskis, & Rimes, 1998) proposes that decision making involves a process of balancing the perceived negative and positive consequences of possible outcomes of each option, weighted according to the beliefs and values of the decision maker at that time, and including anticipated emotional consequences. The theory suggests that the extent to which a person is attending to particular anticipated consequences at the time they are making the decision is likely to be crucial. Factors of which the person is not currently aware are much less likely to influence the outcome. If this is so, then even when information is provided in a non-directive manner (free of bias), then subsequent procedures to support the process of decision making which have the effect of focussing the person's attention on a particular outcome are likely to influence the actual decision taken. Often, such procedures support the patient in eliciting values of possible outcomes, e.g the value of the potential benefits in terms of day-to-day quality of life, or of the potential side effects of the medication. This process of value elicitation would, by definition, be considered 'nondirective' (i.e. absence of deception, threat or coercion (Kessler, 1992; Kessler, 1997), and no provision of advice). However, according to the modified Subjective Expected Utility Theory, even after the provision of unbiased information in Phase 1, this process of value elicitation in Phase 2 could systematically bias the decision outcome.

Several research studies support this theory, demonstrating that the decision outcome is related to the balance of pros and cons on which people focus at that time (e.g. Wroe, 2002; Wroe & Thomas, 2003). In addition, experimental studies have demonstrated that the extent to which a person is attending to particular anticipated consequences at the time they are

making the decision, influences both the hypothetical and actual medical decisions (Rimes, Salkovskis, Bolton & Wroe, 2010; Wroe & Salkovskis, 2000; Wroe, Salkovskis, & Rimes, 2000; Wroe & Salkovskis, 1999). This was the case even when they are implemented in a way that conforms to current definitions of the form of non-directive approaches (Kessler, 1992, 1997).

For example, participants were given a balanced set of information about the pros and cons of bone density screenings as phase 1 of the decision support. Subsequently, as phase 2, they were asked to reflect upon and rate the extent to which the previously given information was personally relevant (described as a focussing intervention). When the focus was mainly on negative items of the previously given information, participants were less likely to express a preference to undergo testing; when positive, more likely to opt for testing. The experimental procedures that were used were designed so that both negative and positive focussing were similar to non-directive reflection, and value elicitation, as used in counselling. It was concluded that even when information is provided in a non-directive way (free of bias), if the subsequent phase of assigning personal relevance to information is biased, there will still be a directive effect, such that focussing on positive or negative aspects in the phase of assigning personal relevance systematically influences the decision outcome.

Understanding treatment preferences and medical decision making is particularly salient given the government's key strategy to ensure that patients are involved in treatment decisions as described in the mandate 'Liberating the NHS: No decision about me, without me' (Department of Health, 2012). It is stated that, 'All patients who wish to be involved in decisions and choices about their treatment and management of their condition should receive the relevant

information and professional support to do so.....possibly facilitated through the use of a patient decision aid to explore their treatment options’ (page 29). Patient decision aids are specifically recommended for decisions about treatment for cholesterol (NHS Right Care, 2012) which include 5 steps:

1. “Introduction: Overview of the decision, options and health problem
2. Compare options: Information about all the options explained side-by-side
3. My Views: Thinking about what matters to you about the decision
4. My Trade-Offs: Weighing up the pros and cons of the options to you
5. My Decision: Make a decision that is right for you at this time”

Throughout this process, patients are to be offered ‘Decision Support’, that is the opportunity to ‘Speak with a Health Coach at any point throughout your decision making process’.

Given this government/NHS supported strategy, it is crucial therefore to understand how people can be helped through each of these steps, in a way that reaches the goal of making a decision that is right at this time. Not only must the patient be must be fully informed, but he/she must also be encouraged to think ‘about matters relevant to’ him/her regarding this decision, and to weigh ‘up the pros and cons’. It is the second part of the decision making that is the focus on this paper. The authors seek to address the question as to how the Health Coach can support the decision in a way that is systematic and unbiased. The modified Subjective Expected Utility Theory would suggest that the Health Coach’s role to support patients in ‘Thinking about what matters to you about the decision’ and ‘Weighing up the pros and cons of the options to you,’ could systematically bias the patient’s decision outcome even if performed in a way that was previously considered ‘nondirective’.

The studies of Wroe and colleagues were carried out in the context of screening decisions. The aim of the present study is to address the issue of whether the focussing effects found in screening generalise to decisions about whether or not to accept a particular treatment. As in the screening studies, there are ethical considerations which constrain experimental studies in this area of research. A hypothetical treatment decision (whether to take cholesterol-lowering medication or not) was therefore the focus of the present investigation. It is hypothesised that, consistent with the modified Subjective Expected Utility Theory, even after unbiased provision of information (phase 1), the issues on which individuals are subsequently encouraged to focus through value elicitation (Phase 2) systematically biases the decision outcome.

Method

Overview

Participants were asked to consider a hypothetical situation in which they were identified as being at risk of heart disease so that treatment with statins would be likely to be helpful. The study then examined how this likelihood was influenced by an experimental manipulation which took the form of an apparently non-directive procedure. Participants were randomly allocated to one of four conditions in which they were induced to focus on: the potentially positive or negative aspects of the treatment decision, a combination, or irrelevant health information. Full ethical approval was given by the local NHS Local Research Ethics Committee.

Participants

Participants were recruited from adults passing by a busy pharmacy shop in Oxford city

centre. Of the people approached one in six agreed to take part in a 10-15 minute interview about health psychology. Those who scored either 100 or 0 on the initial rating of the first question (the anticipated likelihood that they would consider taking statins) were not included in the final sample in order to deal with ceiling and floor effects; in other words, participants who scored 0 or 100 at baseline can, by definition, only change in one direction. This resulted in the exclusion of 25 people scoring 0 and 18 scoring 100, a total of 43 people of whom 22 were male and 21 female. This excluded group did not differ ($p>0.1$) from the total sample in terms of gender or age. The final sample reported here was therefore 146 people. Participants who reported a history of heart problems or high cholesterol were excluded. One participant withdrew from the study as s/he felt unable to concentrate on the questions. The original intention was to have the three experimental groups with 40 participants, with the control group having 20. Selection on the basis of extreme scores on the initial question resulted in slightly uneven cell sizes. There were no significant differences between groups in terms of the baseline measures (see Table 1) ($p>0.15$ in every instance), and the groups did not differ in terms of gender distribution ($p>0.2$).

Procedure

Participants read an information sheet and signed a consent form, and were then asked to imagine a hypothetical situation in which they were identified as being at risk of heart disease by their general practitioner. All participants were given identical information about the prevalence of heart disease, and the benefits and disadvantages of taking medication (statins). At this stage the participants were asked to give ratings of likelihood of opting for testing (on 0-100 scales): (i) the anticipated likelihood that they would consider taking this drug (statins); (ii) the anticipated likelihood that they would take this drug if the doctor recommended it.

Until this stage, the experimenter was unaware of the participant's allocation to experimental condition as randomisation had been pre-arranged for the entire batch of questionnaires.

Thus, the experimental condition was only known to the experimenter once they turned to the focussing questions page. Participants were thus randomly allocated on the basis of the questionnaire sequence to one of the four experimental groups.

Intervention

The focussing groups were: positive focussing; negative focussing; mixed focussing; and control. Each of the groups was then asked to respond to a series of questions on different aspects of the information that was given at the outset - the focussing manipulation questions.

Those in the positive group were encouraged to focus on the previously described possible benefits of taking statins. This was done by asking them to rate the degree to which each statement would apply to them. Participants in this group were asked to rate the applicability of the following positive focussing statements:

-If I had decided to take the statins drug I would be very relieved that my chances of having a heart attack were reduced

-If I had decided to take the statins drug I would feel that at least I had some control over health

-If I had decided to take the statins drug I would be pleased that my high cholesterol levels were being reduced

-If I had decided to take the statins drug I would be pleased that I would be having regular check-ups

-If I had decided to take the statins drug I would feel better that I was taking action towards being a healthier person

-If I had decided to take the statins drug taking the drug each day would remind and motivate me to find out and do all I could to prevent a heart attack

-If I had decided to take the statins drug it would comfort me to know that I might be able to prevent myself having a heart attack

-If I decided not to take statins if I then suffered a heart attack I would regret the decision not to take statins

-If I decided not to take statins I would worry that my cholesterol levels would remain high or become even higher

-How much do you think that it would put your mind at rest knowing that you were doing everything you could to prevent yourself from suffering a heart attack?

Participants in the negative group were encouraged to focus on the previously described negative aspects of taking statins by rating the extent to which they felt the following negative statements would apply to them.

-If I had decided not to take the statins drug I would be glad that I wasn't relying on drugs everyday

-If I had decided not to take the statins drug I would be glad not to have to worry about side effects of this drug

-If I had decided to take the statins drug I would worry the drug hasn't been sufficiently tested to know what long term effects it might have

-If I had decided to take the statins drug I would be upset about having to take a drug for the rest of my life

-If I had decided to take the statins drug, it would be frustrating to take a drug every day especially when I didn't actually feel ill

-If I had decided to take the statins drug it would be troublesome to have to go to my doctor for regular check ups

-If I had decided to take the statins drug if after a long time statins didn't have any significant effect on my cholesterol levels I would regret taking them

-If I had decided to take the statins drug I would be constantly looking out for side effects of the drug

-If I had decided to take the statins drug if I were to suffer long term side effects I would regret having taken the statins drug

-Finally overall, how much do you think that the side-effects and your concerns about them would worsen your quality of life?

Those in the mixed group were asked to rate the applicability of a balanced subgroup of positive and negative statements. The participants in the control group were asked to rate the extent to which they believed that statements about the common cold applied to them.

Following this focussing procedure, participants were asked to summarise briefly the issues which had been discussed and rated. The decision ratings were then repeated.

Treatment of data

Post-manipulation data were analysed using separate repeated measures analyses of covariance, with the baseline (pre-manipulation) point used as covariate. Significant main effects were examined using Tukey-b multiple comparisons.

Results

Overview

The results indicate a significant and differential effect of the positive focussing manipulation

on the rated likelihood of opting for taking statins. Participants in this positive focussing group said that they were more likely to opt for the treatment after the manipulation than other groups. There was no apparent effect of the negative (or other) conditions.

Treatment decision ratings

An analysis of covariance (ANCOVA) for ratings of how likely the person would be to consider taking statins indicated that the experimental condition effect was significant ($F[3, 141]=17.3, p<0.0001$). Multiple comparisons indicate that the rated likelihood that they would consider taking statins was significantly higher in the positive focussing group compared with all other groups (effect size for the post intervention ratings = 0.78). The other groups did not differ from each other. In particular there were no significant differences between the negative focusing group and other groups (effect sizes for the post intervention ratings = 0.24). These results are shown in Table 1 and Figure 1.

Table 1 about here

Figure 1 about here

There was also a significant main effect of condition in the ANCOVA for the rating of how likely they would be to take the drug if the doctor recommended it ($F[3, 141]=4.6, p<0.005$). Multiple comparisons indicated that the positive condition ratings were significantly higher than those in the negative focussing group, and that the remaining comparisons were not significantly different (see Table 1). The effect sizes for the post intervention ratings

compared to the control group were 0.43 for the positive group and 0.31 for the negative group.

As sampling had resulted in slightly (non-significantly) unbalanced gender composition between experimental groups, all analyses were repeated with gender included as a second grouping factor. There was no evidence of any effect of gender ($F < 1.5$ for all effects and measures).

Discussion

The experimental study reported here examined the effect of attending to different aspects of treatment options on a hypothetical treatment decision. The initial information provided to each participant (phase 1 of shared decision making) was identical across groups to ensure that the only difference was the way in which this information was subsequently reflected upon (Phase 2 of shared decision making). The results of this study demonstrated that focussing on positive aspects of treatment outcome was significantly associated with an increase in the rated likelihood of opting for treatment (i.e. taking the medication) compared to the other groups. The effect sizes for the post intervention ratings suggested a medium to large effect of the positive focusing intervention on 'likelihood of opting for treatment' and a small to medium effect on 'likelihood of opting for treatment if the doctor recommended it'. At a power level of 0.8, this suggests that estimated sample sizes of 12 and 35 respectively would be required to obtain significant results using α of 0.5. In comparison, there were no significant differences between the negative focusing group and other groups. The effect sizes for the post intervention rating suggest small effects of the negative focusing on 'likelihood of opting for treatment' and on 'likelihood of opting for treatment if the doctor recommended it'. At a power level of 0.8, estimated sample sizes of 109 and 66 respectively

would be required to obtain significant results using α of 0.5. It is concluded that there is a weak negative effect of the negative focussing on the decision.

The findings in terms of the decision ratings are partly consistent with previous studies involving decisions made about undergoing screening tests. In those studies, individuals who were encouraged to focus on the positive consequences of a going for a screening test were significantly more likely to opt for screening (Rimes et al, 2010; Wroe et al., 2000). Note that, in those studies and in the study reported here, the information provided in phase 1 was identical across conditions and the focussing manipulation in phase 2 was confined to the information given at that earlier stage. These previous studies found that negative focussing significantly reduced the rating of likelihood of opting for screening, with this effect also being reflected in actual screening uptake. There was no sign of such an effect in the present study.

There are several factors which may account for the difference between the present study and the previous ones. The most obvious of these is that the decision involved here was whether or not to accept treatment rather than to undergo screening, as in the previous studies. It may be that this accounts for the difference; for example, it might be that people react completely differently to the contemplation of treatment, or that treatment is simply seen as “a good thing” and therefore would be accepted if offered by a physician and that negative considerations would not affect the acceptance of treatment. However, it is difficult to see how this would not also be the case in health screening procedures.

Comments made by the participants during the debriefing carried out on completion of the

study suggest another explanation. Statins are a particularly benign form of treatment, with relatively few and rare negative effects. The items in the positive focussing condition included benefits such as e.g. “I would be very relieved that my chances of having a heart attack were reduced” and, “If I didn’t take statins and then suffered a heart attack I would regret the decision not to take statins”, whilst negative focussing items were relatively weakly valenced eg. “I would be upset about having to take a drug for the rest of my life” and, “It would be frustrating to take a drug especially when I didn’t actually feel ill”. It may have been that the choice of statins therefore provided a built in imbalance. The research group are completing a further study designed to evaluate the impact of focussing on a treatment decision for which there are more and more severely negative consequences. Subsequent studies will also examine whether the effect observed on an anticipated decision will generalise to the actual decision to accept treatment in the same way as was observed in screening (Wroe et al, 2000).

We chose to sample “in the street” as we had previously found that the samples of convenience obtained in this way gave a good mix of gender, age, educational status and socioeconomic background. We believe that the mix obtained is more representative of the target population (people who might be involved in making decisions about their health) than the use of students. Historically, recruiting outside a pharmacist's shop had allowed the researcher to use the physical context by linking it to the notion of health-related decisions. It is, however, possible that our sampling method (approaching potential participants in a busy street) may have resulted in a biased sample, given that one in six of those approached participated. This sample was selected because true representative sampling is difficult, time consuming and costly, and it is assumed that if the selection criteria do not depart too far

from the population of interest (examples of departures might include exclusive use of students or health care professionals) then at worst sampling effects would mask the true effect size. Consistent with this view, we have subsequently been able to replicate and extend the present findings in a sample of patients in a GPs waiting room, with close to 80% of those invited to participate agreeing to do so (MacInnes, Wroe & Salkovskis, in preparation). A further potential limitation is that the researcher was not blind to the participants' conditions and this may have inadvertently influenced the researcher's manner.

The findings have important implications for the way in which patients are helped to make treatment decisions. As in screening decisions, it may no longer be sufficient to rely on the idea that one has been "non-directive" (as defined by the form of the consultation) in order to respect the need for patient autonomy in decision making. The findings are consistent with research by Michie, French, Allanson, Bobrow, & Marteau, 1997), who suggested that it can be difficult to achieve non-directiveness within a decision-oriented consultation, which involves reflecting the patient's behaviour, thoughts or emotions. Furthermore, historically it was suggested that nondirective therapeutic approaches are unlikely to be achievable (Truax, 1966); this work noted that therapeutic aspects such as 'quoting' what the patient may have said and empathy can be reinforcers, and therefore be directive. He concluded that there are 'significant differential reinforcement effects imbedded in the transactions of client-centred psychotherapy' (pp. 7). It may, however, be possible to take advantage of the impact of focussing to implement behaviour change when this is more or less unequivocally positive (see for example Burgess, Bish, Hunter, Salkovskis, Michell, Whelehan & Ramirez, 2008).

It is important to consider whether the experimental interventions used in the present study

could be regarded as having similarities with the kind of clinical procedures likely to be used by clinicians applying principles of non-directive counselling. This is difficult, as such procedures are poorly defined; when they are defined, it is usually only in terms of what they do not contain (e.g. advice and opinion).

Phase 2 of shared decision making can often be regarded as non-directive because it helps the person to explore the available options and their likely emotional and other consequences without offering advice, guidance or opinion. The current research suggests that this phase of value elicitation, or of assigning personal relevance to information, which may be offered not only by counsellors, but also by doctors or by computerised decision aids, may systematically bias the decision outcome.

It seems more than likely that clinical versions of the procedures we used in this experimental study are currently used in clinical decision making consultations, with the degree of emphasis varying considerably. Note, however, that it is possible that those with a formal training in non-directive counselling may seek to preserve the balance between positive and negative in a specific way. Whether or not this is true is not known at this point, as it has not been investigated.

Recently, Williams, Alderson and Farsides (2002) suggested that “neutrality in the unequal relationship of doctor-patient communication is simply not possible”. This paper is interesting for its qualitative examination of clinicians’ views. Obstetrician 71 on page 344 indicates that he thinks there is little point in encouraging people to think about the negative issues as they are not going to be relevant for a majority of the people. Obstetrician 36 also mentions the difficulty of deciding what to 'put into the discussion' as not everything will be

helpful and it may cause anxiety. He/she states that the difficulty is where you draw the line. Similar ideas are currently being discussed with complex decisions such as MMR immunisation. It has been suggested by some that discussing adverse effects will simply raise anxiety and should be minimised. Although this position is understandable, in recent work we have found the opposite to be true (Wroe, Turner, & Owens, 2005). Williams also highlights that these issues are becoming more 'complex as the Human Genome Project develops' and that counsellors may actually becoming more directive 'behind the smokescreen of the rhetoric of value-neutrality and non-directiveness'.

If the results are considered from a different perspective (such as public health rather than counselling), it might be that the findings could be taken indicating the availability of a set of strategies which might be useful in instances where treatment acceptance and adherence is a major issue and the desirable treatment decision outcome is unambiguous. However, the ethics of using such strategies need close examination, particularly as the previous work on actual uptake of screening indicated that (i) the participants did not accept that their decision had been influenced when debriefed and (ii) the intensive debriefing and attempts by the researchers to undo the effects had no discernible impact on the participant's behaviour.

The findings of this study that participants' hypothetical treatment decisions were systematically influenced by the 'nondirective' approach, is concerning given the emphasis on shared decision making. Strategies are needed which protect patients from the potentially biasing effects of this second phase of shared decision making. It is crucial that a decision aid approach is developed and used by health coaches, counsellors, doctors etc. so that patients achieve unbiased decision support. The current study demonstrates that when individuals

were encouraged to focus on both the negative and the positive information, there was no significant change in decision outcome. It is possible therefore that, until a more systematic means of offering truly non-directive counselling is developed, the best approximation to nondirective decisional support is that of a balance between the focus on positive and negative issues.

Table 1: Characteristics of the experimental groups and pre-and post-interventions ratings

	negative group (N=36)	positive group (N=45)	all-focussing group (N=41)	control group (N=24)	Repeated measures ANOVA
	<u>Mean [SD]</u>	<u>Mean [SD]</u>	<u>Mean [SD]</u>	<u>Mean [SD]</u>	
Age	47.61 [10.75]	49.73 [10.54]	45.54 [9.57]	46.83 [9.40]	n/a
Gender	19 women 17 men	28 women 19 men	23 women 18 men	8 women 15 men	n/a
	<u>Pre mean [SD]</u>	<u>Pre mean [SD]</u>	<u>Pre mean [SD]</u>	<u>Pre mean[SD]</u>	
	<u>Post mean[SD]</u>	<u>Post mean[SD]</u>	<u>Post mean[SD]</u>	<u>Post mean[SD]</u>	
Likelihood they would consider taking statins	50.14 [23.769] 50.55 [22.77]	49.56 [24.38] 74.00 [23.66]	51.34 [24.80] 57.07 [25.27]	52.92 [19.61] 56.04 [22.69]	F[3, 141]=17.3 p<0.0001
Likelihood would take statins if Dr recommended it	62.78 [27.58] 61.25 [24.42]	73.11 [25.70] 80.77 [24.84]	66.83 [25.81] 67.80 [26.57]	69.58 [28.62] 69.38 [28.06]	F[3,141]=4.6 p<0.005

Figure caption

Figure 1: Ratings of likelihood of taking statins by group and time point.

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